

United States Department of Agriculture
Animal and Plant Health Inspection Service
Plant Protection & Quarantine
4700 River Road
Riverdale, MD 20737


Permit to Move Live Plant Pests, Noxious Weeds, and Soil
Interstate Movement
Regulated by 7 CFR 330

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PERMITTEE NAME:	Dr. Frisby Smith	PERMIT NUMBER:	P526P-19-02176
ORGANIZATION:	Bayer US - Biologics	APPLICATION NUMBER:	P526-190522-081
ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	FACILITY NUMBER:	3279
MAILING ADDRESS:	890 Embarcadero Drive West Sacramento, CA 95605	HAND CARRY:	No
PHONE:	916-661-3322	DATE ISSUED:	06/24/2019
FAX:		EXPIRES:	06/24/2022
DESTINATION:	Bayer US - Biologics, 890 Embarcadero Drive, West Sacramento, CA 95605		
RELEASE:	No		

Under the conditions specified, this permit authorizes the following:					
<u>Regulated Article</u>	<u>Life Stage(s)</u>	<u>Intended Use</u>	<u>Shipment Origins</u>	<u>Originally Collected</u>	<u>Culture Designation</u>
Autographa californica nuclear polyhedrosis virus	Lyophilized plant or microbes, Microbial solutions	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	Lepigen and related
Chrysodeixis includens nucleopolyhedrovirus	Lyophilized plant or microbes, Microbial solutions	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	Chrysogen and related
Helicoverpa armigera Nucleopolyhedrovirus	Lyophilized plant or microbes, Microbial solutions	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	Heligen and related
Plutella xylostella Granulovirus PxGV	Lyophilized plant or microbes, Microbial solutions	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	AgBiTech isolates and related
Spodoptera exigua nucleopolyhedrovirus	Lyophilized plant or microbes, Microbial solutions	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	AgBiTech isolates and related
Spodoptera frugiperda SfMNPV	Lyophilized plant or microbes, Microbial solutions	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	Fawligen and related
Spodoptera litura NPV	Lyophilized plant or microbes, Microbial solutions	Research - Growth Chamber (lab included)	Continental U.S.	Originally Collected from Within the Continental U.S.	AgBiTech isolates and related

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<p>THIS PERMIT HAS BEEN APPROVED ELECTRONICALLY BY THE FOLLOWING PPQ HEADQUARTER OFFICIAL VIA EPERMITS.</p> <p></p> <p>Robert Pfannenstiel</p>	<p>DATE</p> <p>06/24/2019</p>
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WARNING: Any alteration, forgery or unauthorized use of this Federal Form is subject to civil penalties of up to \$250,000 (7 U.S.C.s 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C.s 1001)

PERMIT GUIDANCE

- 1) This permit does not authorize movement or release into the environment of genetically engineered organisms produced with the regulated organisms described in this permit. Importation, interstate movement, and environmental release of genetically engineered plant pests require a different permit issued under regulations at 7 CFR part 340. Any unauthorized interstate movement or environmental release, including accidental release, of a regulated GE organism would be a violation of those regulations. Additional guidance and contact information for APHIS Biotechnology Regulatory Services, can be found at: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.
- 2) If an animal pathogen is identified in your shipment, to ensure appropriate safeguarding, please refer to http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports_an_products.shtml
- 3) If a human pathogen is identified, please refer to the CDC Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/>
- 4) This permit does not fulfill the requirements of other federal or state regulatory authorities. Please contact the appropriate agencies, such as the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, the APHIS Veterinary Services unit, the APHIS Biotechnology Regulatory Services, or your State's Department of Agriculture to ensure proper permitting.
- 5) If you are considering renewal of this permit, an application should be submitted at least 90 days prior to the expiration date of this permit to ensure continued coverage. Permits requiring containment facilities may take a longer period of time to process.

PERMIT CONDITIONS

USDA-APHIS issues this permit to Frisby Smith, Bayer US - Biologics, 890 Embarcadero Drive, West Sacramento, CA 95605. This permit authorizes the interstate movement of microbial solutions of Baculoviridae from locations in the Continental U.S. to California for laboratory research in Containment Facility # 3279 (CF# 3279).

1. • This permit is issued by the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). It conveys APHIS regulations and requirements for the material(s) listed on this permit. It does not reduce or eliminate your legal duty and responsibility to comply with all other applicable Federal and State regulatory requirements.
- The permit number or a copy of the permit must accompany the shipment.
- You must be an individual at least 18 years old, or legal entity such as partnership, corporation, association, or joint venture.
- You are legally responsible for complying with all permit requirements and permit conditions.
- If you violate any applicable laws associated with this permit, you may face substantial civil or

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criminal penalties. We may cancel all current permits and deny future permit applications.

- Without prior notice and during reasonable hours, authorized Federal and State Regulators must be allowed to inspect the conditions associated with the regulated materials/organisms authorized under this permit.

2. The permit holder must:

- maintain a valid PPQ526 permit so long as the regulated materials/organisms are alive or viable,
- not assign or transfer this permit to other persons without APHIS PPQ authorization,
- maintain an official permanent work assignment, residence, or affiliation at the address on this permit,
- notify the Pest Permit Staff as soon as possible of any change in the permit holder's work assignment, residence, or affiliation,
- notify the Pest Permit Staff of the receipt of unauthorized and/or misdirected shipments of regulated materials/organisms,
- adequately mitigate environmental impacts resulting from unauthorized release of regulated materials/organisms and notify the Pest Permit staff immediately if one occurs,
- notify the Pest Permit Staff if the facility is damaged/destroyed or if you wish to decommission the facility,
- destroy all regulated materials/organisms prior to departure from the organization unless other arrangements are confirmed by the Pest Permit Staff.

Notifications to the Pest Permit Staff must be made via 866-524-5421 or pest.permits@aphis.usda.gov within one business day of the event triggering a notification.

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3. All packages for transport must minimally consist of both inner/primary and outer/secondary packages securely sealed so that both are effective barriers to escape or unauthorized dissemination of the listed materials/organisms. The inner/primary package(s) will contain all regulated materials/organisms and must be cushioned and sealed in such a way that it remains sealed during shock, impact, and pressure changes that may occur. The outer/secondary shipping container must be rigid and strong enough to withstand typical shipping conditions (dropping, stacking, impact from other freight, etc.) without opening.
4. This permit authorizes the possession of live organisms of only the Baculoviridae received as authorized under this permit. Live cultures of other species from other hosts and sources are not authorized under this permit.
5. These organisms are to be maintained only in the laboratory area approved for containment at the work address indicated on this permit (CF 3279). Distribution or other removal from the designated area of Containment Facility 3279 requires a separate prior authorization from APHIS PPQ (= amendment to this permit, or a separate 526 permit).

This permit does not authorize field release, interstate transport, field research, or any other activities with the Baculoviridae listed here outside of the containment facility.


6. All operations must be consistent with information submitted in association with this Containment Facility (CF3279) including the most recent Standard Operating Procedures (SOP's) submitted for the Facility, and any information submitted in association with the inspection of this Containment Facility. This includes, minimally, maintenance of restricted access to unauthorized persons of building and or approved containment areas (key, key card or code), and/or restricted access to unauthorized persons of growth chambers and other equipment (for example by lock) where organisms will be kept, as well as proper/prescribed maintenance of the Autoclave and/or other equipment used to devitalize or sterilize waste.

Procedures must be in place to retain the regulated articles (permitted cultures) and media and substrate exposed to the cultures and inoculum during testing and screening, such as soil, pots and plants, and subject all such materials, inoculum and cultures of the species imported under this permit to procedures which will effectively devitalize the organisms and or properly dispose of these items as per adopted and approved laboratory protocols.

7. The permit holder must insure that all persons working with these regulated organisms a) are trained in the importance of approved containment practices; b) follow the Standard Operating Procedures (SOP) established for the facility and filed with the USDA APHIS Pest Permit Evaluation Unit at the time of facility inspection; and c) are informed of these permit conditions and understand the requirement to adhere to these conditions and the SOP.

The permit holder shall document such training or familiarization with these permit conditions and the SOP's for the facility, by having copies of both dated and signed/initialed by all persons handling the regulated articles, and have such documentation made available to USDA APHIS upon request.


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8. Upon receipt (and removal) of organisms regulated under this permit, all biological and non-biological material, including primary and, secondary shipping containers shall be handled and/or disposed of as per laboratory and containment facility SOP. Secondary containers, outer shipping containers and packing materials (such as cushioning material, icepacks) may be reused, only after sterilization as per approved protocol.
9. Upon completion of research (unless a new PPQ 526 permit is received which authorizes possession and use of these organisms), all cultures and infected arthropods shall be devitalized, and soil, or anything that has contacted the regulated organism (such as glassware pots and other containers will be likewise decontaminated by autoclaving or incineration, appropriate use of fresh bleach solution of 10 percent (1:9), 70 percent alcohol or quaternary ammonium compounds, or other effective procedure as per laboratory SOP.

END OF PERMIT CONDITIONS

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